MacEwan UNIVERSITY | RESEARCH ETHICS BOARD

SOP 406.01

Title	Ongoing REB Review Activities
SOP Code	406.01
Effective Date	September 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	*Original signed*	October 2020
Dr. Craig Kuziemsky, AVPR	*Original signed*	September 2023

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for REB review of ongoing research activities that occur after the initial Research Ethics Board (REB) approval of a research project and outside of the formally scheduled continuing review of the research project.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

The Researcher is responsible for reporting to the REB any unanticipated issues that may arise or proposed changes that are needed through the course of the research that might affect the rights, safety and well-being of research participants.

The REB Chair or designee is responsible for reviewing the reports or proposed changes, and for determining the type of review (i.e., delegated or Full Board) or action required.

The REB members are responsible for reviewing the reports or proposed changes that are assigned to them or that are assigned to a Full Board meeting, and for recommending the appropriate course of action.

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Unanticipated issues may arise during the course of research that may impact the risk/benefits ratio and/or may require that changes are made to the project; therefore, in addition to the formally scheduled continuing review, the REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such information, submitted using the ROMEO platform, may include:

- Proposed modifications to the previously approved research,
- Reports of unanticipated events involving risks to participants or others,
- Reports of privacy breaches,
- Deviations from the previously approved research,
- Any other new information that my affect adversely the safety of the research participants or the conduct of the research,

Modifications to the approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the Researcher must notify the REB immediately.

5.1 Modifications to the Approved Research

5.1.1 The Researcher is responsible for submitting to the REB any proposed changes to the approved research in the form of a modification request. Changes to the approved research include modifications to the research, to the consent form, changes in participant materials (e.g., recruitment materials), a change in the Researcher etc.;

5.1.2 When the modification includes a change to the consent form, the Researcher must indicate their recommendation for the provision of the new information to current and/or past research participants;

5.1.3 The Researcher should indicate the new level of risk the research poses by incorporating the change, and the type of review being requested (i.e., Full Board, delegated review or acknowledgement for a minor correction or change). Supporting documentation and/or background information may be appended to the modification submission;

5.1.4 The REB Chair or designee reviews the modification to determine the appropriate level of REB review required (i.e., Full Board, delegated or in-office review);

5.1.5 The REB Chair or designee also may use delegated review procedures for review of modifications when the conditions are met:

5.1.6 If the proposed change represents more than minimal risk, it must be reviewed by the REB at a Full Board meeting.

5.1.7 For modifications requiring Full Board review, the responsible REB Office Personnel assigns the modification to the next available Full Board meeting. For modifications that meet the criteria for delegated review, the responsible REB Office Personnel will forward the modification to the designated reviewer;

5.1.8 When a modification involves a revised consent, the REB will consider the recommendations of the Researcher in determining if, how and when the new information should be provided to the research participants and whether re-consent is required;

5.1.9 The REB must find that the criteria for approval are still met in order to approve the modification;

5.1.10 The modified research may not be implemented prior to the REB review and approval, except when necessary to eliminate immediate hazards to participants.

5.2 Unanticipated Issues

5.2.1 The Researcher is responsible for reporting any unanticipated issue or event that may increase the level of risk to participants, or have other ethical implications for participants;

5.2.2 Any unanticipated issue that may increase the level of risk to participants or may impact participants' welfare should be reported immediately to the REB;

5.2.3 The researcher should indicate whether the unanticipated issue was directly related to the research and whether changes to the protocol are necessary to reduce the chance of recurrence;

5.2.4 If changes are necessary, a modification request should be submitted in addition to the unanticipated event report.

5.3 Deviations to Previously Approved Research

5.3.1 Deviations from the approved protocol that are necessary to eliminate an immediate risk(s) to the participants may be implemented, but must be reported to the REB at the earliest opportunity.

5.3.2 Deviations that occur through the course of the research that may impact the risk assessment of the research or have other ethical implications,

should be reported to the REB as soon as possible. If a permanent change is required, a modification request should be submitted.

5.3.3 Minor deviations from the research that do not impact risk or have ethical implications may be summarized in annual status reports.

5.4 Privacy Breaches

5.4.1 The Researcher must report to the REB any unauthorized collection, use or disclosure of personal information including, but not limited to:

- The collection, use and disclosure of personal information that is not in compliance with jurisdictional requirements
- Circumstances where personal information is stolen, lost or subject to unauthorized use or disclosure or where records of personal information are subjected to unauthorized copying, sharing, modifications or disposal,
- In the Research context, any unauthorized collection, use or disclosure of personal information that was not authorized under the research and approved in the plan that was submitted to the REB.

The breach must be reported to the REB and to the MacEwan's Privacy Office as soon as the Research becomes aware of the breach.

5.5 Review of Reportable Events by the REB

5.5.1 The responsible REB Office Personnel will screen the submission form for completeness;

5.5.2 The REB Office Personnel may route the submission back to the Researcher to request clarifications, missing documents or additional information;

5.5.3 The REB Office Personnel will forward the submission to the designated REB reviewer(s);

5.5.4 The assigned REB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;

5.5.5 The assigned reviewer(s) may request further information from the Researcher;

5.5.6 When reviewing the report, the REB should:

- Assess the appropriateness of any proposed corrective or preventative measures by Researcher,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the Researcher,

- Consider whether the affected research still satisfies the requirements for REB approval; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics approval of the research is warranted;

5.5.7 If the event does not raise concerns and does not appear to involve risks to research participants or others, the REB Chair or designee acknowledges the report, and no further action is required;

5.5.8 If the REB Chair or designee determines that immediate action is required to protect the safety of research participants, they may suspend ethics approval of the research pending review by the Full Board, providing the justification for such action is documented;

5.5.9 If the event raises concerns or involves risk to research participants such that REB action may be required, the item is added to the agenda of the next Full Board meeting;

5.5.10 For reports reviewed at a Full Board meeting, the REB determines whether further action is required. Possible actions that could be taken by the REB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,
- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency of continuing review,
- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- Allegation of non-compliance or research misconduct in accordance with the institution's policy and procedures.

5.5.11 If the REB determines that the event does not raise concerns about risks to research participants, the REB may decide that no further action needs to be taken;

5.5.12 When action is taken to ensure the protection of the rights, safety, and well-being of participants the REB chair or designee is responsible for reporting to the Researcher and the Institutional Official(s).

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
404.00	October 8 2020	Original version
404.01	September 2023	Reviewed, revised ‘amendment’ to ‘modification’, addition of information regarding privacy breaches in 5.4